494270

Washington

June 28, 2001

Mr. Tony Medrano
Regional Quality Assurance Officer
EPA Region VIII, 8TMS-Q
999 18th Street, Suite 500
Denver, CO 80202

REF: RAC No. 68-W7-0039
WA Nos. 004-RICO-089R, 007-RICO-085G, 009-RICO-085G

SUBJECT: Quality Assurance Audit of Paragon Analytics, Inc.

Dear Tony:

Attached is the Paragon Analytics, Inc. laboratory audit report prepared by Washington Group International, Inc. Washington Group has a service agreement with Paragon Analytics for analytical services under our RAC. Washington Group has utilized Paragon for metals analysis of Vasquez Blvd/I-70 OU1 soils and investigation derived waste, as well as metals, volatile organics, semivolatile organics, and pesticides/PCB analyses of Intermountain Waste Oil Refinery waste samples.

We will forward documentation of corrective actions completed to address the audit findings. If you have any questions regarding this audit, please contact our Quality Assurance Manager, Paul Bell, at (303)843-3204.

Sincerely,

Marta Green
RAC Program Manager

Attachment

Cc (w/attach): B. Lavelle, 8EPR-SR
L. Lloyd, 8EPR-SR
M. Goldade, 8EPR-SR
P. Bell, Washington Group
A. Sacha, Washington Group

Cc (w/o attach): J. Powell, 8EPR-SR

5555 Greenwood Plaza Blvd., Suite 100 • Englewood, Colorado USA 80111 • P.O. Box 5888 • Denver, Colorado USA 80217
Phone: (303) 843-2000 • Fax: (303) 843-2208 • www.wgint.com

Paul Bell

From: Paul Bell [paul.bell@wgint.com]
Sent: Thursday, July 12, 2001 1:08 PM
To: Debra Henderer [henderer@paragonlabs.com]
Cc: Marta Green; April Sacha
Subject: Overdue Audit Response

Dear Ms Henderer,

Currently Paragon Analytics response to Washington Group International, Inc. Quality Assurance Audit Report No. RAC-V-01-01 is overdue. It is urgent that your response is submitted to us on time. Our client the US EPA Region 8 Quality Assurance Manager has inquired regarding your response. The deficiencies noted during the audit and the formal corrective actions being formulated by your company are important to us and our client. Since we have not received your response or a request for an extension, our client the US EPA has voiced some concerns regarding the status, disposition, and formal corrective actions regarding this audit. As you are aware it is important to maintain good working relationships with our clients, therefore please provide Washington Group International the status of your response, and the date in which your response will be submitted.

Sincerely,

Paul Bell

Washington Group International, Inc.
Regional Quality Assurance Manager

Washington

June 08, 2001

Debra Henderer
Quality Assurance Manager
Paragon Analytics, Inc.
225 Commerce Drive
Fort Collins, CO. 80525

SUBJECT: **Washington Group International, Inc. Quality Assurance Audit Report No. RAC-V-01-01 of Paragon Analytics, Inc.**

Dear Ms. Henderer:

Enclosed for your review and subsequent response is the Washington Group International Inc. Quality Assurance Audit Report No. RAC-V-01-01 of activities at Paragon Analytics, Inc. located in Fort Collins, Colorado. The audit was conducted on May 08, 2001, to verify, by examination and evaluation of objective evidence, the ability of your Laboratory to provide Chemical Analytical Analysis. In addition, the scope of this audit was inclusive of verifying Paragon Analytics', Inc. capability to perform work as stipulated in the October 18, 1999 Subcontract 1D9-4994-SC01.

Based on the overall results of the audit, and in the opinion of the audit team, it appears that Paragon Analytics, Inc. has some minor programmatic problems as identified in the attached report that will require immediate corrective action.

This audit investigation covered (2) separate scopes of work. Since each of the respective work scopes were uniquely interrelated, the audit report is therefore subdivided into subsections which are inclusive of the following:

1. Compliance to current Chemical QA Program and applicable EPA requirements

2. Compliance to existing Subcontract 1D9-4994-SC02 Items

The audit resulted in seven (7) Quality Findings and two (2) Observations, which are documented in the attached report. Upon completion of corrective action implementation of each itemized post-award survey item, those items shall be forwarded with objective evidence with the completed audit responses. It should be emphasized that the following items must be addressed in a concise manner for each of the Quality Findings and Observation:

a. The steps, which have or will be taken to correct the condition reported;
b. The root cause that led to the condition reported;
c. The steps taken to prevent recurrence;
d. Lessons learned (if applicable);
e. The dates when indicated action was or will be completed.

Washington

Corrective Actions to all items requiring response shall be both concise and to the point.

The "original" audit report is attached for distribution to the appropriate personnel for inclusion of the required responses. Please submit your responses in the spaces provided on the attached "original" form. The original form should then be transmitted back to the Regional Quality Assurance Office for evaluation.

Should you have any questions regarding our approved vendor program, please contact me at (303) 843-2022.

Sincerely,

Washington Group International

David C. Lambert Laura M. Bern for David C. Lambert

DCL

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Phone: (303) 843-2000 • Fax: (303) 843-2208 • www.wgint.com

Washington

WASHINGTON GROUP INTERNATIONAL, INC. QUALITY ASSURANCE
AUDIT REPORT NO. RAC-V-01-01

Date 05/08/01

TO: Ms. Debra Henderer

FROM: David C. Lambert

LEAD AUDITOR:
(Signature) Paul M. Bell for David C. LAMBERT

AUDIT DATES: May 08, 2001

RESPONSE DUE DATE: July 8, 2001

ORGANIZATION Washington Group International, Inc. (Denver Regional Office)

ACTIVITY AUDITED: Paragon Analytics, Inc. Laboratory Quality Assurance Activities

PURPOSE/SCOPE: The scope of this audit was to evaluate Paragon Analytics Inc. implementation of laboratory quality program for activities and environmental testing protocols being performed at their facility in Fort Collins, CO. This audit was performed in support of the U.S. EPA Response Action Contract (RAC). These projects are inclusive of the Vasquez Boulevard/Interstate-70 (VB/I-70) site in Colorado, the Intermountain Waste Oil Refinery (IWOR) and the Eureka Mills site in Utah. The audit was initiated to verify compliance with Quality Assurance guidelines specified in both the VB/I-70 Phase IIIB QAPP and the IWOR Phase I QAPP.

AUDIT TEAM:
- Team Leader – D. C. Lambert
- Auditor - P. M. Bell
- Subject Matter Expert – A. Sacha

PERSONNEL CONTACTED DURING AUDIT:

Name	Title
See Attachments A and B	

SUMMARY:

The purpose and scope of the audit was presented at a pre-audit conference held on May 08, 2001, at Paragon Analytics facility located in Fort Collins, CO. The audit was performed in accordance with a written checklist of applicable laboratory QA program requirements. The audit results were derived based on interviews of personnel, review of records and logbooks, inspection of instruments, and the evaluation of QA Program procedure implementation. Audit results were presented to the appropriate Paragon Analytics, Inc personnel at the post-audit conference held on May 08, 2001.

The audit resulted in seven (7) minor Findings and two (2) Observations which are included in the attached report. With the exception of the noted Findings and Observations, the audited Laboratory

QA Program elements and criteria were determined to be in compliance with the QA program requirements and effectively implemented.

The audit team would like to thank all Paragon personnel contacted during the course of this audit.

The following good laboratory practices or noteworthy items were observed during the audit investigation and all responsible personnel should be commended for their professionalism.

- All employees are provided with dosimeter badges to be worn while in radiation areas.
- General laboratory housekeeping was good throughout the laboratory.
- Current staffing levels and evening/weekend coverage are excellent in regards to urgent turn-around times.
- Internal Chain-of Custody forms used for sample receipt to analysis to archival to disposal are organized and fully implemented.
- Good chemical hygiene was observed by the use of MSDS sheets, clear labeling of chemicals, solvents and standards. Containers in use were noted to retain the appropriate custody log-out documentation inclusive of the analyst initials and opened date on the container.
- The waste generation and disposal program currently in place is outstanding.
- All customer service provided to date by the Project Manager has been excellent.

In conclusion, the Paragon Analytic's Laboratory sample analysis and data validation is within acceptable limits to meet Washington Group International Inc. needs, provided the deficient items addressed throughout this audit report are satisfactorily corrected and verified through follow-up.

1. ORGANIZATION AND RESPONSIBILITIES

The organizational structure is adequately described in the Paragon Analytics LQAP, Section 2, and further illustrated in Appendix A of the LQAP. Activities and responsibilities are further defined and delineated in the LQAP.

Satisfactory compliance.

2. LABORATORY QUALITY ASSURANCE PROGRAM

The Paragon Analytics' Laboratory Quality Assurance Plan (LQAP Revision 4, dated 02/99) was reviewed. The frequency of internal reviews and revisions to the LQAP as stated are not being performed within the established frequency of once every two years. Review of Paragon Analytics LQAP indicated that many stated procedural requirements are not currently being practiced in the laboratory. A review of LQAP Section 16.2 revealed that Paragon was previously classified as a small quantity waste generator whereas now, Paragon is classified as a large quantity waste generator. Further review of Paragon LQAP, Section 15.1, stated that all laboratory employees who engage in laboratory activities are required to submit to annual physical examinations in accordance with the Laboratory's Medical Surveillance Program.

Nine (9) Laboratory Standard Operating Procedures (SOPs) were reviewed. SOP 409, Revision 0, (PCB Analysis), and SOP 525, Revision 4, (GC/MS VOA Analysis) were not up-dated bi-annually as specified in Paragon LQAP Section 1.5.2.

Additionally laboratory control limits and the associated control charts were reviewed. However, laboratory control limits and the control limit update frequency were not being re-calculated annually or semi-annually as required by US EPA Method SW-846-8000B, Section 8.7.5. During this audit, there were no records or personnel files to substantiate whether these programmatic elements are currently being implemented.

Reference Audit Finding Report (AFR) No. 01

3. QUALITY ASSURANCE OBJECTIVES

The objectives specified and defined within the Paragon Analytic's Laboratory Quality Assurance Program, Standard Operating Procedures and Program Specifications were reviewed during this audit. Review of various quality-affecting documents indicated that laboratory quality assurance objectives are being met through controlled distribution, preparation, and completion of laboratory protocols, with the exception of items identified throughout this report.
The majority of the laboratory activities were in compliance with laboratory procedures, with the exception of documents such as; (LQAP annual review, control limit calculations, and training records) which do not currently meet the objectives outline in Revision 4 of the LQAP.

Reference Audit Finding Report (AFR) No. No. 02

4. SAMPLE PRESERVATION, HOLDING TIMES AND HANDLING PROCEDURES

Sample preservation, holding times and handling procedures were reviewed. The laboratory sampling, preservation and handling protocols were assessed to ensure that scientific data is legally defensible and are in accordance with the protocols specified by USEPA Contract Laboratory Program.

Satisfactory compliance.

5. SAMPLE CUSTODY

Sample Internal Chain-of-Custody compliance was verified by visual inspection of the Sample Custody receipt and storage area. All sample custody activities inclusive of chain-of-custody, data validity, checkout and storage were verified as meeting the appropriate U.S. EPA requirements.

Satisfactory compliance.

6. ANALYTICAL PROCEDURES

Analytical Procedures were reviewed to verify compliance to the analytical protocols prescribed by various EPA Methods and compliance to the detailed requirements specified in each respective procedure. During the course of the audit, the audit team noted observations regarding analytical procedural protocols as follows:

- There is currently no solvent testing program in place (as specified by LQAP Section 17.2)
- Monthly supervisory reviews of laboratory logbooks are not being performed on a routine basis

Unsatisfactory Compliance

Reference Audit Observation Report (AOR) No.1

7. CALIBRATION PROCEDURES AND FREQUENCY

Calibration procedures and calibration frequencies were reviewed. The requirements for the calibration of laboratory scales/balances, and the calibration of instrumentation used throughout the laboratory was verified and validated against instrument calibration logs. Calibration frequencies are being maintained as well as, calibration stickers were verified as being affixed to instruments that required calibration.

Satisfactory Compliance

8. PREVENTIVE MAINTENANCE

The Paragon Preventative Maintenance Program was reviewed for adequacy and effectiveness. During the audit, a broken and/or not in use GC/MS pump and GC OI Purge and Trap was observed in an auspicious location. Further investigation indicated that the GC/MS pump and GC OI Purge and Trap were not labeled with the appropriate status indicator or tag-out tag as specified by SOP 319.

Unsatisfactory

Reference Audit Finding Report (AFR) No. 4

9. QUALITY CONTROL PROCEDURES

Internal Paragon Laboratory Quality Control Procedures were reviewed to determine the in-house systematic process controls implemented to measure and detect errors or out-of-control events. In-house quality controls are defined and implemented through various procedures. The criterion that is used to measure and analyze environmental data includes measurements of accuracy and precision. However, the control limit measurements that are required to reflect the degree to which the measured value approximates the actual or true value for a given

parameter and the control limits which influence bias in measurements are not being updated semi-annually or annually for some methods as required by EPA Method Protocols.

Unsatisfactory

Reference Audit Finding Report (AFR) No. 3

10. DATA REDUCTION, VALIDATION AND REPORTING

Data reduction, validation and reporting of information throughout the laboratory was reviewed and verified. Work Order No. 0103075 was reviewed. During the audit team's review the following observations were noted:

- Many organic laboratories were missing the annotation of the amounts of various standards added to samples during prep or analysis on the run log books
- Corrections to sample extraction and preparation laboratory [illegible] for ignitability or GC pesticide data were not corrected with [illegible] date.
- Manual integrat[illegible] view of GC/MS SVOA and Pe[illegible] integration and subsequent in[illegible]
- Case narrative[illegible] aled that dilutions were initiated f[illegible] de an explanation or reason as to[illegible] rtaining why undiluted samp[illegible]

UN-Satisfactory

Reference Audit Obs[illegible]

11. PERFORMANCE AN[illegible]

This verification incluc[illegible] [illegible]s and completed audits.

The laboratory initiates two types of audits used to verify and assess laboratory compliance. A review of Paragon's audit program indicated that laboratory audits are being performed. However, internal performance and systems audits are not being performed at the frequency of once per month as specified in the LQAP.

Unsatisfactory compliance.

Reference Audit Finding Report (AFR) No.6

12. QUALITY ASSURANCE REPORTS TO MANAGEMENT

Reports to management were verified by review of nonconformance reports. The audit team reviewed various nonconformance reports and corresponding dispositions. Routine NCR dispositions such as; "use-as-is", "reject" and/or "repair" are not marked on the NCR form. Objective evidence of the disposition process indicated that in many cases the disposition was recorded as "Document in a Narrative". Further investigation indicated that in most cases, the narrative is undefined and is not attached or part of the disposition and closure of the NCR.

The NCR system does not provide adequate confidence that the nonconformance reporting and subsequent corrective actions are being dispositioned to preclude recurrence and are being tracked from initiation through closure.

Unsatisfactory

Reference Audit Finding Report (AFR) No.5

13. CORRECTIVE ACTIONS

Laboratory Corrective Actions were reviewed. The corrective action program is in place. However, a review of audit results and subsequent corrective actions indicate that follow-up of corrective action implementation strategies are not being initiated within two weeks of report issuance as procedurally required. A review of the audit log indicated that a series of audits were performed in 1999 and 2000. The corrective actions to these audits were not noted as being either closed or that the corrective actions were completed.

UnSatisfactory

14. PERSONNEL TRAINING

Washington Group International was provided Paragon Training Documentation records for review. There was no objective evidence to substantiate department/laboratory specific training or subsequent checklists. Review of training records indicated that there was missing documentation attesting to the analytical staff's credentials (i.e., resumes, educational backgrounds, diploma's etc.) Additionally the following training records were noted as being incomplete: required Paragon LQAP training, Radiation Training RCRA Training etc. The training documentation that was reviewed did not summarize each analyst initial proficiency demonstrations (as specified in SW-846 and Paragon LQAP, Revision4 Section 14.2.2.2)

UnSatisfactory

Reference Audit Finding Report (AFR) No. 02

15. LABORATORY SAFETY

The Paragon Laboratory Safety protocols were reviewed by both visual inspection of laboratory areas and of in place programs. In general, the laboratory safety programs and personnel exhibit adequate knowledge to safely perform their assigned duties. Health and safety training was reviewed for various laboratory personnel. The Paragon medical surveillance program, which is inclusive of an annual physical examination for all employees, engaged in laboratory activities, is required by procedure. Training records indicate that no Paragon personnel have been given an annual physical as specified in the LQAP.

Unsatisfactory.

Reference Audit Finding Report (AFR) No. 02

16. LABORATORY WASTE DISPOSAL

The laboratory waste disposal was reviewed for various waste streams. The waste streams that are being generated are now of significant enough quantities to classify the laboratory as a large quantity waste generator. Currently the LQAP Section 16.2 classifies Paragon Laboratory as a small quantity waste generator, which does not coincide with the current waste generator classification.

Unsatisfactory

Reference Audit Finding Report (AFR) No. 01

17. PROCUREMENT CONTROL

Various procurement records were reviewed to assure legibility, traceability to associated items and, that they accurately reflect the work accomplished. Procurement records indicate that secondary source standards are being purchased from a different suppler than primary standards. Additionally, some procurement documents are not being reviewed or approved by cognizant supervision for quality affecting requirements such as, Certificates of Calibration, certificates of purity, NIST traceability etc.

Unsatisfactory Compliance.

Reference Audit Observation Report (AOR) No. 01

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization: Paragon Analytics, Inc.	Location: Fort Collins, CO	Evaluation Date(s) 05/08/01

Subject
Evaluation of Paragon Analytics, Inc. Laboratory Quality Assurance Program

References:
Paragon Analytics Laboratory Quality Assurance Program Revision 4 dated 02/99

Evaluation Performed by:

Dave C. Lambert Lead Auditor
Paul M. Bell Auditor
April Sacha Subject Matter Expert

Item	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
1.	Verify that the latest revision(s) of SOP's are available and present in all laboratories. Additionally, verify that the following personnel have signed-off on the completed document:: • Group Leader or technically competent staff member • Laboratory QA Manager • Laboratory Manager	(Section 1.5.2)	Sat			
2.	Verify that SOPs are distributed as controlled documents and QA has maintained a distribution list of each SOP.	Section 1.5.2,	Sat			
3.	Are MDLs run on each instrument and each matrix?	Section 3.7		Un-sat		
4.	Review and verify that Method Detection Limits (MDLs) are ran at a frequency that provides consistency in meeting the Method Reporting Limit (RL). Are MDLs run annually?	Section 3.7		Un-Sat		
5.	Review internal chain-of-custody procedural protocols from receipt to archival. Are samples signed-out when removed for analysis? Ensure that the sample custody log references the following: • Sample identification • Date/time • Analyst • Laboratory of analysis	Section 5.8.1	Sat			

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

Item	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
6.	Review and verify that all instruments used throughout the laboratory are traceable to NIST, EPA or other nationally recognized standards. Review and compare Paragon Equipment Lists of all major instrumentation. Sample equipment listed on the equipment list and the associated calibration certificates.	Section 7	Sat			
7.	Are all standards traceable? Review Standards Notebooks ensure that standards are stored in a manner as prescribed in Paragon LQAP Table 7-1.	Section 7	Sat			
8.	Verify that each standard is identified with an internal identification number. Ensure that stock standards are documented in the Standards Notebook by listing the following: • Date of preparation • The analyst • The source of the reference material • Amounts used • Final volume • Serial number	Section 301	Sat			
9.	What is the GC/MS VOA preparation frequency for standards containing gases? Verify that the preparation frequency is documented. Review actual samples of gaseous standards.	Section 302	Sat			
10.	Are diluted working standards not consumed during an analytical session fully labeled, including the serial reference number of stock standards used in its preparation?	Section 7.2	Sat			
11.	Verify that calibration standards are chosen to bracket the expected concentration level of those concentration levels of the parameter contained within the sample. Ensure that calibration standards are prepared at a minimum of three concentration levels or (3-5 times) and (5-10 times) the estimated method detection limit plus a calibration blank.	Section 7.3		Un-Sat		

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

Item	Attributes	Paragon LQAP	Sat	Un-sat	N/A	Comments
12.	Verify that the accuracy of prepared standards is periodically checked by comparison with a standard from an independent source. Additionally, verify that a second source standard (initial calibration verification or (IVC) after the initial calibration and the responses of the second source calibration and the standards are compared against one another.	Section .7.3		Un-Sat		
13.	Verify that pH meters, balances and turbidity meters are calibrated daily with NIST traceable reference material. In addition ensure the following calibration frequencies are maintained: • Analytical Balances – every 12 months entire range) • Electrometer/pH – prior to use and once every four hours of use (calibrated with three buffer solutions)	Section .7.3	Sat			
14.	Verify that Gas Chromatography user range calibrations are initiated by obtaining a three or five point calibration curve, consisting of all compounds of interest plus a calibration blank.	Section .7.6.1	Sat			
15.	Verify that the laboratory participates in the EPA-LV/EMSL Interlaboratory Comparison Program.	Section 9.2.2,	Sat			
16.	Verify that when Gas Chromatography and Mass Spectrometry is performed the following operational parameters are adhered to satisfy analytical requirements associated with the determination of organic compounds in water and soil sediment: • Documentation of GC/MS mass calibration • Documentation of GC/MS response factor stability • Internal standard response and retention time	Section 7.6.2		Un-Sat		
17.	Verify that water utilized to prepare most LCSs analysis is analyzed for conductivity and water dispensing stations are tested on a weekly basis and results are recorded on the Water Conductance Log sheets	Section 9.2.2,	Sat			

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

Item	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
18.	Verify that the laboratory possesses a valid radioactive materials license.	Section 9.2.2,	Sat			
19.	Are efficiency control charts plotted on a daily basis, reviewed by the QA/QC department once tri-monthly, when either graph value to be reported falls on or above the +2 sigma or on or below the -2 sigma is the QA department notified?	Section 9.4.2	Sat			
20.	Review and verify that for Method 8000B per section 8.7.5 control limits are update semi-annually. Additionally, review and verify the frequency in which laboratory control charts are updated.	Section 9.4.1		Un-Sat		
21.	During Matrix Spike Sample Analysis, at what concentration percentage is each analyte in order to be within the linear range of the spiked sample solution. In addition is the acceptability of the control limit for a spike between 75-125% recovery.	Section 9.2.2	Sat			
22.	Verify that analytical spike sample analysis is being added after samples are prepared and prior to analysis and are run at a frequency of 5%.	Section 9.2.2	Sat			
23.	Verify that Laboratory Control Samples are ran independently with every batch of analysis and utilized for the verification of the internal standard from which the calculations are made.	Section 9.2.2	Sat			
24.	Verify that two (2) standard deviations are used for 95% confidence intervals during the calculation of control charts for the ICAP, and for each batch of samples analyzed the following QC checks are initiated: • At least one blank analyzed • At least one LCS (spiked with all reported analytes • MS/MSD pair analyzed • One sample duplicate analyzed • One sample dilution (dilution factor =5) • Initial multi-point calibration (3 to 6 standards plus a calibration blank) • One-point calibration verification standard compared against the initial calibration curve • Second source calibration verification standard. • A interference check standard at the beginning and end of the run • Drift check standard analyzed between every 10 field samples and at end of analysis run	Section 500	Sat			

Organization:	Location:	Evaluation Date(s)

	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
25.	Verify that tracking of standards, chemicals, and reagents used in inorganic chemistry are logged in a bound logbook and the following information is maintained within: a. Date chemical/regent is opened b. Standard number c. consecutive numbered tape d. Identification e. Manufacturer, lot number etc. d. Mixing information e. noted mixing instructions f. Expiration date g. shelf life instructions f. Numbering system	Section 10.3	Sat			
26.	Ensure that Level 2 reviews of data packages include the following: • Group leader independent review • Calibration data are scientifically sound, appropriate to the method and completely documented. • QC Samples are within established guidelines • Quantitative identification of sample components is correct • Quantitative results are correct • Documentation is complete • Data package is complete.	Section 10.3	Sat			
27.	Review and verify that data reduction, validation and reporting are entered into the LIMS.		Sat			
28	Review and verify Paragon laboratory safety protocols. Are safety showers, fire extinguishers, etc., inspected? Additionally, verify the following: • Hazard Communication Program including MSDS use. • Use disposal of chemical reagents, chemical standards, and analysis samples • Medical surveillance program including physical examinations of employees			Un-Sat		
29	Is a record of Preventative Maintenance kept in the instrument log book for each piece of analytical equipment and is the tasked performed, date, and the person(s) performing the PM task logged into the log book		Sat			

QUALITY ASSURANCE

Organization:		Location:				Evaluation Date(s)
	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
30.	Verify that Level 2 reviews are structured to include 10 percent checks of calibration data and QC sample results and the results are against bench sheets. Additionally, when discrepancies Level 2 data packages are found, verify that an additional 10 percent of the samples are checked against bench sheets.	Section 10.4,	Sat			
31.	Verify that the following internal audits are performed to assess and document performance of the laboratory staff in the following frequencies: a. Monthly Systems Audits	Section 11.1,		Un-Sat		
32.	Review and verify that performance audits are documented and include the following: • Documentation of refrigerator blanks • Inspection/surveillance of temperature logbooks for refrigerators and ovens • Calibrations of mechanical pipettes	Section 11.1		Un-Sat		
33.	Are audit results and subsequent corrective actions (e.g., follow-up) verified within two weeks of report issuance?	Section 11.1		Un-Sat		
34.	Review and verify the latest external systems audit of the following agencies: • State of Colorado Department of Health • State of Utah Department of Health • State of California Department of Health Services • State of Arizona Department of Health Services • US Army Corps of Engineers •	Section 11.1 Section 11.2.1	Sat			

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
46.	Review and verify that training records for all analytical staff members are being documented and maintained. Ensure that training records include the following as a minimum: • Records of academic training pertinent to the employees work assignment • Summaries of training seminars attended while employed at Paragon • Results of comprehensive testing or training • Results of Health and Safety instruction received at Paragon • Results of proficiency demonstrations as specified in Section 14.2.2 of the LQAP • Current resume if available	Section 14.3		Un-Sat		
47.	Review and verify that Paragon participates in inter-laboratory evaluation programs as sponsored by the following agencies: • US EPA Water Pollution and Water Supply Study Audit Program • State of California Department of Health Services Hazardous Waste PE Program • Department of Energy (DOE), Office of Environmental Management (OEM) Quality Assessment Program • EPA National Exposure Research Laboratory Characterization Research Division • Environmental Resource Associates Proficiency Testing Program (quarterly)		Sat			

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 01 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 1.5.1 states, "The LQAP is main guidance document for laboratory operations when there exists no other project or program-specific requirements to which the laboratory must conform. This document will be reviewed and updated at a minimum frequency of once every two years or more frequently if there are significant changes in procedures or capabilities in the laboratory."

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Laura Barr DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE		VERIFICATION OF IMPLEMENTATION	
Accept [ ]		Accept [ ]	
Reject [ ]		Reject [ ]	
		Not Required [ ]	
SIGNATURE/TITLE	DATE	SIGNATURE/TITLE	DATE

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 01 Page 2 of 2

FINDING: Contrary to the above requirements, it was determined that:

1. Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, has not been revised since February 1999. The Paragon Analytics, Laboratory Quality Assurance Plan has not been updated or revised since February 1999 which exceeds the minimum review and updated frequency as specified in the LQAP. During the course of the audit, Washington Group had noted many discrepancies between what was stated in the LQAP and what is currently being practiced in the laboratory.

2. The following discrepancies were noted:

   Paragon Analytics LQAP Revision 4 Section 16.2 – Laboratory Waste Disposal

   Waste Storage: "Paragon is classified as a small quantity generator, and generates between 100kg and 1000 kg of waste per month. Because of this rate of waste generation, waste materials created at the laboratory may accumulate on the site for a maximum of nine months, depending upon location of the Temporary Storage and Disposal Facility." Contrary to this requirement, Paragon's waste generator classification has changed from a small quantity generator to now a large quantity waste generator, which is not accurately reflected in Section 16.2 of the LQAP.

   Paragon Analytics LQAP Revision 4 Section 15.1 – Laboratory Safety

   Health and Safety Training – "The goal of Health and Safety (H&S) training is to ensure that the laboratory personnel have adequate knowledge to safely perform their assigned duties. This training is presented by laboratory's H&S Officer Health and Safety training is provided to each employee as soon as possible after beginning work. The components of this course include, but are not limited to the following:

   - An explanation of the Medical Surveillance Program, which includes annual physical for all employees engaged in laboratory activities."

   Standard Operating Procedures LQAP Revision 4, Section 1.5.2

   "Standard Operating Procedures (SOPs) are documents that describe in detail how laboratory procedures will be performed by the staff. SOPs will be reviewed and updated at a minimum frequency of once every two years or more frequently if there are significant changes (e.g., SW-846 update)."

   Contrary to the above requirement, biannual updates or revisions to the following Standard Operating Procedures were not revised at the minimum biannual frequency as specified:

   SOP 409, Revision 0, dated 02/15/1999– Analysis of Polychlorinated Biphenyls (PCBs) By Gas Chromatography – Method 8082

   SOP 525, Revision 4, dated 02/12/1999 – Determination of Volatile Compounds By Gas Chromatography/Mass Spectrometry – Method 8260B and Method 624

RECOMMENDED CORRECTIVE ACTION:

Paragon Analytics Inc. should revise the LQAP to reflect the current manner in which business is being conducted in the laboratory. Standard Operating Procedures should also be revised in a timely manner. Since the LQAP is the basic document that represents an overview of laboratory functions, these procedural protocols should accurately reflect the methodologies used throughout the laboratory.

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 02 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 14.3 Training Records states, "Training records for all staff members will be maintained by the Paragon Quality Assurance Department. Training files may contain (but are not limited to) the following information:

1. Records of academic training pertinent to the employee's work assignment
2. Summaries of any training seminars attended while employed at Paragon
3. Any test results for examinations taken at Paragon
4. Records of Health &Safety instruction received while at Paragon
5. If available, a current resume of the employee

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Laura M. Barr DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE		VERIFICATION OF IMPLEMENTATION	
Accept [ ]		Accept [ ]	
Reject [ ]		Reject [ ]	
		Not Required [ ]	
SIGNATURE/TITLE	DATE	SIGNATURE/TITLE	DATE

FINDING: Contrary to the above requirements, it was determined that:

There is no objective evidence that Paragon Laboratory personnel have received laboratory department specific training or checklist thereof. Additionally, credentials attesting to the education, qualifications, and resumes of various staff personnel were either missing or incomplete. Further review of training records indicated that laboratory analysts/ technicians do not have documentation on file indicating that they have completed LQAP training, RCRA Waste training, etc. U.S Environmental Protection Agency Method SW-846 8000B mandates that the results of an analysts initial proficiency demonstration be posted to the individual training file or included in training records.

RECOMMENDED CORRECTIVE ACTION:

Washington Group International, Inc Response Action Contract in support of the U.S. EPA mandates strict compliance to EPA Methods and laboratory protocols. Training records should be updated to document training proficiencies, and the results of training proficiencies included in each analyst file. In general, training records provide the necessary assurance that laboratory personnel are trained, qualified and that they are proficient at their assigned task. Paragon Laboratory QA Manager should assess all training records and update all personnel training files as specified in LQAP Section 14.2.2.2 and SW-846 8000B.

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 03 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 9.0 Quality Control Procedures states, "A quality control program is a systematic process that controls the validity of analytical results by measuring the accuracy and precision of each method and matrix, developing expected control limits, using these limits to detect errors or out of control events, and requiring corrective action measures to prevent or minimize the recurrence of these events." EPA Method 8000B Determinative Chromatographic Separations paragraph 8.7.5 states Once established, control limits and warning limits for spike compounds should be reviewed after every 10 – 20 matrix spike samples of the same matrix, and updated at least semi-annually. Control limits and warning limits for surrogates should be reviewed after every 20 – 30 field samples of the same matrix, and should be updated at least semi annually. The laboratory should track trends in both performance and in the control limits themselves. The control and warning limits used to evaluate the sample results should be those in place at the time the sample was analyzed. Once limits are updated, those limits should apply to all subsequent analyses of new samples.

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Paul M. Bem DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE

Accept [ ]
Reject [ ]

SIGNATURE/TITLE _____ DATE _____

VERIFICATION OF IMPLEMENTATION

Accept [ ]
Reject [ ]
Not Required [ ]

SIGNATURE/TITLE _____ DATE _____

FINDING: Contrary to the above requirements, it was determined that:

Internal Paragon Laboratory Quality Control Procedures were reviewed to determine the in-house systematic process controls implemented to measure and detect errors or out-of-control events. In-house quality controls are defined and implemented through various procedures. The criterion that is used to measure and analyze environmental data includes measurements of accuracy and precision. However, control limit measurements that are required to reflect the degree to which the measured value approximates the actual or true value for a given parameter. The control limits, which influence bias in measurements, are not being updated semi-annually or annually for some methods as required by EPA Method Protocols.

RECOMMENDED CORRECTIVE ACTION:

Washington Group International, Inc Response Action Contract in support of the U.S. EPA mandates strict compliance to EPA Methods and laboratory protocols. The control limits, which influence bias in measurements, should be updated semi-annually or annually as required by EPA Method Protocols. In general, process controls provide the necessary assurance that laboratory processes can measure and detect out-of control events. Paragon Laboratory QA Manager should update all applicable control limit measurements as specified in LQAP and SW-846 8000B.

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 04 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 8.0, Preventative Maintenance states, "The objective of Paragon's preventative maintenance program is to establish a system of instrument care that prevents the loss of analytical quality control and results in the minimum of lost productivity due to instrument failure."

1.

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Paul M. Bem DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE		VERIFICATION OF IMPLEMENTATION	
Accept [ ]		Accept [ ]	
Reject [ ]		Reject [ ]	
		Not Required [ ]	
SIGNATURE/TITLE	DATE	SIGNATURE/TITLE	DATE

FINDING: Contrary to the above requirements, it was determined that:

During the course of the audit, a GC/MS pump and GC OI Purge and Trap located in a laboratory was observed as being set off to the side. Careful examination of the instrumentation indicated that it was not in use and/or it was broken. Further investigation revealed that the item was not properly tagged indicating it's operating status as required by Paragon SOP 319.

RECOMMENDED CORRECTIVE ACTION:

The Washington Group International, Inc audit team recommends that the appropriate tags be place on instrumentation or equipment that is placed out of service, broken or malfunctioning. Additionally, instrumentation should be placed in a designated area that is segregated from all other instrumentation to prevent inadvertent placement of the instrumentation into service or inadvertent use.

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 05 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 12.0, Quality Assurance Reports to Management states, "For day-to-day reporting, A Nonconformance Report (NCR) is initiated for laboratory QA situations that require immediate attention. The employee that discovers the nonconformance is responsible for initiating the NCR. The Project Manager and QA Manager must approve the corrective action proposed. Section 13.1 Nonconformance Report further states, "Nonconformance Reports (NCRs) are controlled documents that are administered by Paragon's Quality Assurance Group. The staff member will then complete the form by entering all pertinent information and the final disposition required to adequately address the Non-Conformance".

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Laura M. Barr DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE

Accept [ ]
Reject [ ]

SIGNATURE/TITLE _____ DATE _____

VERIFICATION OF IMPLEMENTATION

Accept [ ]
Reject [ ]
Not Required [ ]

SIGNATURE/TITLE _____ DATE _____

FINDING: Contrary to the above requirements, it was determined that:

During the course of this audit, Reports to management were verified by review of nonconformance reports. The audit team reviewed various nonconformance reports and corresponding dispositions. Routine NCR dispositions such as; use as is, reject and/or repair are not marked on the NCR form. Objective evidence of the disposition process indicated that in many cases the disposition was recorded as "Document in a Narrative". Further investigation indicated that in most cases, the narrative is undefined and is not attached or part of the disposition and closure of the NCR.

The NCR system does not provide adequate confidence that the nonconformance reporting and subsequent corrective actions are being disposition to preclude recurrence and are being tracked from initiation through closure.

RECOMMENDED CORRECTIVE ACTION:

The Washington Group International, Inc audit team recommends that Nonconformance reports include those documents e.g., Documented Narratives to be included in the final resolution/disposition and corrective action verification of nonconformance reports.

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 06 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 11.0, Performance and System Audits states, "Two types of internal audit procedures will be used to assess and document performance of laboratory staff: systems audits and performance evaluation audits." Section 11.1.1 Internal Systems Audits states, "This audit is general in nature, and provides an overview of laboratory operations. This type of audit must be performed at least once a month unless an external audit is performed during the same calendar month. The laboratory QA Manager will perform the laboratory system audit in accordance with checklists designed to aid the auditor in ensuring that all areas of laboratory operations are reviewed." Section 11.1.1 further states... "Audit results are reported in writing to responsible management for review and corrective action if necessary. A maximum of two weeks is given to respond to the original report."

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Lance M. Barr DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE		VERIFICATION OF IMPLEMENTATION	
Accept [ ]		Accept [ ]	
Reject [ ]		Reject [ ]	
		Not Required [ ]	
SIGNATURE/TITLE	DATE	SIGNATURE/TITLE	DATE

FINDING: *Contrary to the above requirements, it was determined that:*

During the course of this audit, a schedule of audits and corresponding audit reports were reviewed. However, the audit schedule indicated that scheduled examinations of the operations of specific analytical departments were logged as being initiated, but were never formally closed or subsequent corrective actions taken or noted. Additionally, the specified performance frequency e.g. (once per month) in many cases is being exceeded by two or three month intervals. Careful examinations of the audits that have been initiated to date clearly indicate that the evaluation and implementation of specific quality related systems should be improved. The following internal audits were log as being initiated or performed, however the audit report and subsequent corrective actions were not available for review:

Audit No.	Department	Date
IA12199	GC Fuels	01/31/00
IA032000	Metals Rad	04/17/00
	GC SVOC M8081A	06/12/00
	GC SVOC M8082	06/17/00
SR07100	Internal C of C	07/31/00
Unknown	GC/MS/VOC	08/16/00
Unknown	GC Fuels Instrument PC & Backup	09/28/00
Unknown	Organic Extractions Prep & Analysis	10/16/00

In addition, SOP-937 Revision 2, paragraph 2.2, Internal Laboratory Audits specifies that audits will be performed by designated staff, which may or may not use an auditing aid such as checklists. The laboratory audits that were reviewed did not include checklists.

RECOMMENDED CORRECTIVE ACTION:

The Washington Group International, Inc audit team recommends that Performance Audits be conducted at the intervals specified in Section 11.1.1 of Paragon's LQAP. If internal laboratory audits can not be performed or scheduled as specified in the LQAP, then the LQAP should be revised to accommodate a more flexible schedule. Corrective actions to audit deficiencies are to be reported to management for review and corrective actions. The above noted audits were logged as being completed. However, records could not substantiate if the appropriate corrective actions were reviewed verified and effectively implemented. Additionally, the requirement specified in LQAP section 11.1.1 and SOP 937 contradict. The audit team recommends to use checklists as specified or revise the LQAP to be more compatible with the requirements specified in SOP 937. Please provide in your response corrective actions taken to preclude recurrence.

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 07 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 13, Corrective Actions states, "Corrective action is necessary when any measurement system fails to follow this LAQP... In general, items needing corrective action fall into two "correction categories" short term and long term. Long Term Corrective Actions The actions consist of minor and major problems which require a series of actions to resolve the problem. The actions to be taken are coordinated by the Section Manager or QA Manager, and a Non Conformance Report (Appendix D) is used to document the action. The report will describe the analysis involved, the data, analyst, the identification of all affected or suspect samples, probable cause, the corrective action measure(s) taken, and the final disposition/resolution of the problem."

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Paul M. Bem DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE		VERIFICATION OF IMPLEMENTATION	
Accept [ ]		Accept [ ]	
Reject [ ]		Reject [ ]	
		Not Required [ ]	
SIGNATURE/TITLE	DATE	SIGNATURE/TITLE	DATE

FINDING: Contrary to the above requirements, it was determined that:

During the course of this audit, a schedule of audits and corresponding audit reports were reviewed. However, the audit schedule indicated that scheduled examinations of the operations of specific analytical departments were logged as being initiated, but were never formally closed or subsequent corrective actions taken or noted. Additionally, the specified performance frequency e.g., (once per month) in many cases is being exceeded by two or three month intervals. Careful examinations of the audits that have been initiated to date clearly indicate that the evaluation and implementation of specific quality related systems should be improved. The following internal audits were logged as being initiated or performed, however the audit report and subsequent corrective actions were not available for review:

Audit No.	Department	Date
IA12199	GC Fuels	01/31/00
IA032000	Metals Rad	04/17/00
	GC SVOC M8081A	06/12/00
	GC SVOC M8082	06/17/00
SR07100	Internal C of C	07/31/00
Unknown	GC/MS/VOC	08/16/00
Unknown	GC Fuels Instrument PC & Backup	09/28/00
Unknown	Organic Extractions Prep & Analysis	10/16/00

In addition, SOP 937 Revision 2, paragraph 2.2, Internal Laboratory Audits specifies that audits will be performed by designated staff, which may or may not use an auditing aid such as checklists. The laboratory audits that were reviewed did not include checklists.

RECOMMENDED CORRECTIVE ACTION:

The Washington Group International, Inc audit team recommends that corrective actions of audit deficiencies be formulated for and closed for the items noted above. If internal laboratory audits are scheduled but can not be performed as scheduled then the audit log should annotate that the audit could not be performed. Additionally, corrective actions to audit deficiencies are to be reported to management for review, the above noted audits were logged as being completed. However, records could not substantiate if the appropriate corrective actions were reviewed verified and effectively implemented. Additionally, the requirement specified in LQAP Section 11.1.1 and SOP 937 contradict. The audit team recommends the use of checklists, as specified or revise the LQAP to be more compatible with the requirements specified in SOP 937. Please provide in your response corrective actions taken to preclude recurrence.

Washington	AUDIT OBSERVATION REPORT	AOR No.:1 AUDIT No.: RAC-V-01-01

ACTIVITY: Analytical Laboratory Audit CLIENT: U.S. Environmental Protection Agency

ORGANIZATION: Paragon Analytics Inc.

STATEMENT OF REQUIREMENTS:

Paragon Analytics Laboratory Quality Assurance Program Revision 4, Section 17.1 Receipt Verification of Standards states "All primary reference standard and standard solutions are purchased from reliable commercial sources. Standards traceable to NIST are preferred; however, ASTM or equivalent specifications are acceptable. Certification records of all standards received are retained".

Section 17.2 Receipt Verification of Solvents and Acids states "The verification procedure for organic solvents involves taking an initial volume of solvent and concentrating it to a reduced final volume. The initial volume used for this procedure and its final volume vary depending upon solvent...

OBSERVATION

A review of various Purchase Orders indicated that quality related or quality affecting items do not receive quality assurance review. Purchase Order Number 001869 and P.O. 23867 was reviewed. During review it was noted that the items being purchased were not reviewed or approved.

Contrary to the above requirement the audit team could not verify that a solvent testing program is currently in place as specified in section 17.2 of the LQAP.

Classification: **Major** [X] **Minor** [ ] Response Due Date:07/08/01

AUDITOR Paul M. Bucy DATE 06/08/01

OBSERVATION RESPONSE Major Observations only

SIGNATURE TITLE Lead Auditor DATE :

Washington	AUDIT OBSERVATION REPORT	AOR No.:2 AUDIT No.: RAC-V-01-01

ACTIVITY: Analytical Laboratory Audit CLIENT: U.S. Environmental Protection Agency

ORGANIZATION: Paragon Analytics Inc.

STATEMENT OF REQUIREMENTS:
The following observations were made of laboratory practices that of noteworthy. No response is required.

OBSERVATION

Monthly supervisory reviews of laboratory logbooks are not being performed on a consistent basis

The small hood in the GC laboratory is being used for standard preparation when it is only designed for nuisance odor use.

Classification: **Major** ☐ **Minor** ☒ Response Due Date: N/A No Response Required

AUDITOR Paul M. Bu DATE 06/08/01

OBSERVATION RESPONSE Major Observations only

N/A No response Required

SIGNATURE TITLE Lead Auditor DATE :

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 03 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 9.0 Quality Control Procedures states, "A quality control program is a systematic process that controls the validity of analytical results by measuring the accuracy and precision of each method and matrix, developing expected control limits, using these limits to detect errors or out of control events, and requiring corrective action measures to prevent or minimize the recurrence of these events." EPA Method 8000B Determinative Chromatographic Separations paragraph 8.7.5 states Once established, control limits and warning limits for spike compounds should be reviewed after every 10 – 20 matrix spike samples of the same matrix, and updated at least semi-annually. Control limits and warning limits for surrogates should be reviewed after every 20 – 30 field samples of the same matrix, and should be updated at least semi annually. The laboratory should track trends in both performance and in the control limits themselves. The control and warning limits used to evaluate the sample results should be those in place at the time the sample was analyzed. Once limits are updated, those limits should apply to all subsequent analyses of new samples.

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Paul M. Bem DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE

Accept [ ]
Reject [ ]

SIGNATURE/TITLE _____ DATE _____

VERIFICATION OF IMPLEMENTATION

Accept [ ]
Reject [ ]
Not Required [ ]

SIGNATURE/TITLE _____ DATE _____

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 03 Page 2 of 2

FINDING: Contrary to the above requirements, it was determined that:

Internal Paragon Laboratory Quality Control Procedures were reviewed to determine the in-house systematic process controls implemented to measure and detect errors or out-of-control events. In-house quality controls are defined and implemented through various procedures. The criterion that is used to measure and analyze environmental data includes measurements of accuracy and precision. However, control limit measurements that are required to reflect the degree to which the measured value approximates the actual or true value for a given parameter. The control limits, which influence bias in measurements, are not being updated semi-annually or annually for some methods as required by EPA Method Protocols.

RECOMMENDED CORRECTIVE ACTION:

Washington Group International, Inc Response Action Contract in support of the U.S. EPA mandates strict compliance to EPA Methods and laboratory protocols. The control limits, which influence bias in measurements, should be updated semi-annually or annually as required by EPA Method Protocols. In general, process controls provide the necessary assurance that laboratory processes can measure and detect out-of control events. Paragon Laboratory QA Manager should update all applicable control limit measurements as specified in LQAP and SW-846 8000B.

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 04 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 8.0, Preventative Maintenance states, "The objective of Paragon's preventative maintenance program is to establish a system of instrument care that prevents the loss of analytical quality control and results in the minimum of lost productivity due to instrument failure."

1.

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Paul M. Bem DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE		VERIFICATION OF IMPLEMENTATION	
Accept [ ] Reject [ ]		Accept [ ] Reject [ ] Not Required [ ]	
SIGNATURE/TITLE	DATE	SIGNATURE/TITLE	DATE

FINDING: Contrary to the above requirements, it was determined that:

Washington	WASHINGTON GROUP QUALITY ASSURANCE - AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 04 Page 2 of 2

During the course of the audit, a GC/MS pump and GC OI Purge and Trap located in a laboratory was observed as being set off to the side. Careful examination of the instrumentation indicated that it was not in use and/or it was broken. Further investigation revealed that the item was not properly tagged indicating it's operating status as required by Paragon SOP 319.

RECOMMENDED CORRECTIVE ACTION:

The Washington Group International, Inc audit team recommends that the appropriate tags be place on instrumentation or equipment that is placed out of service, broken or malfunctioning. Additionally, instrumentation should be placed in a designated area that is segregated from all other instrumentation to prevent inadvertent placement of the instrumentation into service or inadvertent use.

Washington	WASHINGTON GROUP QUALITY ASSURANCE - AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 05 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 12.0, Quality Assurance Reports to Management states, "For day-to-day reporting, A Nonconformance Report (NCR) is initiated for laboratory QA situations that require immediate attention. The employee that discovers the nonconformance is responsible for initiating the NCR. The Project Manager and QA Manager must approve the corrective action proposed. Section 13.1 Nonconformance Report further states, "Nonconformance Reports (NCRs) are controlled documents that are administered by Paragon's Quality Assurance Group. The staff member will then complete the form by entering all pertinent information and the final disposition required to adequately address the Non-Conformance".

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Laura M. Barr DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE		VERIFICATION OF IMPLEMENTATION	
Accept [ ]		Accept [ ]	
Reject [ ]		Reject [ ]	
		Not Required [ ]	
SIGNATURE/TITLE	DATE	SIGNATURE/TITLE	DATE

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 05 Page 2 of 2

FINDING: Contrary to the above requirements, it was determined that:

During the course of this audit, Reports to management were verified by review of nonconformance reports. The audit team reviewed various nonconformance reports and corresponding dispositions. Routine NCR dispositions such as; use as is, reject and/or repair are not marked on the NCR form. Objective evidence of the disposition process indicated that in many cases the disposition was recorded as "Document in a Narrative". Further investigation indicated that in most cases, the narrative is undefined and is not attached or part of the disposition and closure of the NCR.

The NCR system does not provide adequate confidence that the nonconformance reporting and subsequent corrective actions are being disposition to preclude recurrence and are being tracked from initiation through closure.

RECOMMENDED CORRECTIVE ACTION:

The Washington Group International, Inc audit team recommends that Nonconformance reports include those documents e.g., Documented Narratives to be included in the final resolution/disposition and corrective action verification of nonconformance reports.

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 06 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 11.0, Performance and System Audits states, "Two types of internal audit procedures will be used to assess and document performance of laboratory staff: systems audits and performance evaluation audits." Section 11.1.1 Internal Systems Audits states, "This audit is general in nature, and provides an overview of laboratory operations. This type of audit must be performed at least once a month unless an external audit is performed during the same calendar month. The laboratory QA Manager will perform the laboratory system audit in accordance with checklists designed to aid the auditor in ensuring that all areas of laboratory operations are reviewed." Section 11.1.1 further states... "Audit results are reported in writing to responsible management for review and corrective action if necessary. A maximum of two weeks is given to respond to the original report."

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Lance M. Barr DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE

Accept [ ]
Reject [ ]

SIGNATURE/TITLE _____ DATE _____

VERIFICATION OF IMPLEMENTATION

Accept [ ]
Reject [ ]
Not Required [ ]

SIGNATURE/TITLE _____ DATE _____

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 06 Page 2 of 2

FINDING: Contrary to the above requirements, it was determined that:

During the course of this audit, a schedule of audits and corresponding audit reports were reviewed. However, the audit schedule indicated that scheduled examinations of the operations of specific analytical departments were logged as being initiated, but were never formally closed or subsequent corrective actions taken or noted. Additionally, the specified performance frequency e.g. (once per month) in many cases is being exceeded by two or three month intervals. Careful examinations of the audits that have been initiated to date clearly indicate that the evaluation and implementation of specific quality related systems should be improved. The following internal audits were log as being initiated or performed, however the audit report and subsequent corrective actions were not available for review:

Audit No.	Department	Date
IA12199	GC Fuels	01/31/00
IA032000	Metals Rad	04/17/00
	GC SVOC M8081A	06/12/00
	GC SVOC M8082	06/17/00
SR07100	Internal C of C	07/31/00
Unknown	GC/MS/VOC	08/16/00
Unknown	GC Fuels Instrument PC & Backup	09/28/00
Unknown	Organic Extractions Prep & Analysis	10/16/00

In addition, SOP-937 Revision 2, paragraph 2.2, Internal Laboratory Audits specifies that audits will be performed by designated staff, which may or may not use an auditing aid such as checklists. The laboratory audits that were reviewed did not include checklists.

RECOMMENDED CORRECTIVE ACTION:

The Washington Group International, Inc audit team recommends that Performance Audits be conducted at the intervals specified in Section 11.1.1 of Paragon's LQAP. If internal laboratory audits can not be performed or scheduled as specified in the LQAP, then the LQAP should be revised to accommodate a more flexible schedule. Corrective actions to audit deficiencies are to be reported to management for review and corrective actions. The above noted audits were logged as being completed. However, records could not substantiate if the appropriate corrective actions were reviewed verified and effectively implemented. Additionally, the requirement specified in LQAP section 11.1.1 and SOP 937 contradict. The audit team recommends to use checklists as specified or revise the LQAP to be more compatible with the requirements specified in SOP 937. Please provide in your response corrective actions taken to preclude recurrence.

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 07 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 13, Corrective Actions states, "Corrective action is necessary when any measurement system fails to follow this LAQP... In general, items needing corrective action fall into two "correction categories" short term and long term. Long Term Corrective Actions The actions consist of minor and major problems which require a series of actions to resolve the problem. The actions to be taken are coordinated by the Section Manager or QA Manager, and a Non Conformance Report (Appendix D) is used to document the action. The report will describe the analysis involved, the data, analyst, the identification of all affected or suspect samples, probable cause, the corrective action measure(s) taken, and the final disposition/resolution of the problem."

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: *See attached page 2.*

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Paul M. Bem DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE		VERIFICATION OF IMPLEMENTATION	
Accept [ ] Reject [ ]		Accept [ ] Reject [ ] Not Required [ ]	
SIGNATURE/TITLE	DATE	SIGNATURE/TITLE	DATE

FINDING: Contrary to the above requirements, it was determined that:

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 07 Page 2 of 2

During the course of this audit, a schedule of audits and corresponding audit reports were reviewed. However, the audit schedule indicated that scheduled examinations of the operations of specific analytical departments were logged as being initiated, but were never formally closed or subsequent corrective actions taken or noted. Additionally, the specified performance frequency e.g., (once per month) in many cases is being exceeded by two or three month intervals. Careful examinations of the audits that have been initiated to date clearly indicate that the evaluation and implementation of specific quality related systems should be improved. The following internal audits were logged as being initiated or performed, however the audit report and subsequent corrective actions were not available for review:

Audit No.	Department	Date
IA12199	GC Fuels	01/31/00
IA032000	Metals Rad	04/17/00
	GC SVOC M8081A	06/12/00
	GC SVOC M8082	06/17/00
SR07100	Internal C of C	07/31/00
Unknown	GC/MS/VOC	08/16/00
Unknown	GC Fuels Instrument PC & Backup	09/28/00
Unknown	Organic Extractions Prep & Analysis	10/16/00

In addition, SOP 937 Revision 2, paragraph 2.2, Internal Laboratory Audits specifies that audits will be performed by designated staff, which may or may not use an auditing aid such as checklists. The laboratory audits that were reviewed did not include checklists.

RECOMMENDED CORRECTIVE ACTION:

The Washington Group International, Inc audit team recommends that corrective actions of audit deficiencies be formulated for and closed for the items noted above. If internal laboratory audits are scheduled but can not be performed as scheduled then the audit log should annotate that the audit could not be performed. Additionally, corrective actions to audit deficiencies are to be reported to management for review, the above noted audits were logged as being completed. However, records could not substantiate if the appropriate corrective actions were reviewed verified and effectively implemented. Additionally, the requirement specified in LQAP Section 11.1.1 and SOP 937 contradict. The audit team recommends the use of checklists, as specified or revise the LQAP to be more compatible with the requirements specified in SOP 937. Please provide in your response corrective actions taken to preclude recurrence.

Washington	**AUDIT OBSERVATION REPORT**	AOR NO.:1 AUDIT NO.: RAC-V-01-01

ACTIVITY: Analytical Laboratory Audit CLIENT: U.S. Environmental Protection Agency

ORGANIZATION: Paragon Analytics Inc.

STATEMENT OF REQUIREMENTS:

Paragon Analytics Laboratory Quality Assurance Program Revision 4, Section 17.1 Receipt Verification of Standards states "All primary reference standard and standard solutions are purchased from reliable commercial sources. Standards traceable to NIST are preferred; however, ASTM or equivalent specifications are acceptable. Certification records of all standards received are retained".

Section 17.2 Receipt Verification of Solvents and Acids states "The verification procedure for organic solvents involves taking an initial volume of solvent and concentrating it to a reduced final volume. The initial volume used for this procedure and its final volume vary depending upon solvent...

OBSERVATION

A review of various Purchase Orders indicated that quality related or quality affecting items do not receive quality assurance review. Purchase Order Number 001869 and P.O. 23867 was reviewed. During review it was noted that the items being purchased were not reviewed or approved.

Contrary to the above requirement the audit team could not verify that a solvent testing program is currently in place as specified in section 17.2 of the LQAP.

Classification: **Major** [X] **Minor** [ ] Response Due Date:07/08/01

AUDITOR [signature] DATE 06/08/01

OBSERVATION RESPONSE Major Observations only

SIGNATURE TITLE Lead Auditor DATE :

Washington	AUDIT OBSERVATION REPORT	AOR No.:2 AUDIT No.: RAC-V-01-01

ACTIVITY: Analytical Laboratory Audit CLIENT: U.S. Environmental Protection Agency

ORGANIZATION: Paragon Analytics Inc.

STATEMENT OF REQUIREMENTS:
The following observations were made of laboratory practices that of noteworthy. No response is required.

OBSERVATION

Monthly supervisory reviews of laboratory logbooks are not being performed on a consistent basis

The small hood in the GC laboratory is being used for standard preparation when it is only designed for nuisance odor use.

Classification: **Major** ☐ **Minor** ☒ Response Due Date: N/A No Response Required

AUDITOR Paul M. Bar DATE 06/08/01

OBSERVATION RESPONSE Major Observations only

N/A No response Required

SIGNATURE TITLE Lead Auditor DATE :

Washington	AUDIT OBSERVATION REPORT	AOR No.:2 AUDIT No.: RAC-V-01-01

ACTIVITY: Analytical Laboratory Audit CLIENT: U.S. Environmental Protection Agency

ORGANIZATION: Paragon Analytics Inc.

STATEMENT OF REQUIREMENTS:
The following observations were made of laboratory practices that of noteworthy. No response is required.

OBSERVATION

Monthly supervisory reviews of laboratory logbooks are not being performed on a consistent basis

The small hood in the GC laboratory is being used for standard preparation when it is only designed for nuisance odor use.

Classification: **Major** ☐ **Minor** ☒ Response Due Date: N/A No Response Required

AUDITOR Paul M. Bu DATE 06/08/01

OBSERVATION RESPONSE Major Observations only

N/A No response Required

SIGNATURE TITLE Lead Auditor DATE :

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization: Paragon Analytics, Inc.	Location: Fort Collins, CO	Evaluation Date(s) 05/08/01

Subject
Evaluation of Paragon Analytics, Inc. Laboratory Quality Assurance Program

References:
Paragon Analytics Laboratory Quality Assurance Program Revision 4 dated 02/99

Evaluation Performed by:

Dave C. Lambert Lead Auditor
Paul M. Bell Auditor
April Sacha Subject Matter Expert

Item	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
1.	Verify that the latest revision(s) of SOP's are available and present in all laboratories. Additionally, verify that the following personnel have signed-off on the completed document:: • Group Leader or technically competent staff member • Laboratory QA Manager • Laboratory Manager	(Section 1.5.2)	Sat			
2.	Verify that SOPs are distributed as controlled documents and QA has maintained a distribution list of each SOP.	Section 1.5.2,	Sat			
3.	Are MDLs run on each instrument and each matrix?	Section 3.7		Un-sat		
4.	Review and verify that Method Detection Limits (MDLs) are ran at a frequency that provides consistency in meeting the Method Reporting Limit (RL). Are MDLs run annually?	Section 3.7		Un-Sat		
5.	Review internal chain-of-custody procedural protocols from receipt to archival. Are samples signed-out when removed for analysis? Ensure that the sample custody log references the following: • Sample identification • Date/time • Analyst • Laboratory of analysis	Section 5.8.1	Sat			

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

Item	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
6.	Review and verify that all instruments used throughout the laboratory are traceable to NIST, EPA or other nationally recognized standards. Review and compare Paragon Equipment Lists of all major instrumentation. Sample equipment listed on the equipment list and the associated calibration certificates.	Section 7	Sat			
7.	Are all standards traceable? Review Standards Notebooks ensure that standards are stored in a manner as prescribed in Paragon LQAP Table 7-1.	Section 7	Sat			
8.	Verify that each standard is identified with an internal identification number. Ensure that stock standards are documented in the Standards Notebook by listing the following: • Date of preparation • The analyst • The source of the reference material • Amounts used • Final volume • Serial number	Section 301	Sat			
9.	What is the GC/MS VOA preparation frequency for standards containing gases? Verify that the preparation frequency is documented. Review actual samples of gaseous standards.	Section 302	Sat			
10.	Are diluted working standards not consumed during an analytical session fully labeled, including the serial reference number of stock standards used in its preparation?	Section 7.2	Sat			
11.	Verify that calibration standards are chosen to bracket the expected concentration level of those concentration levels of the parameter contained within the sample. Ensure that calibration standards are prepared at a minimum of three concentration levels or (3-5 times) and (5-10 times) the estimated method detection limit plus a calibration blank.	Section 7.3		Un-Sat		

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

Item	Attributes	Paragon LQAP	Sat	Un-sat	N/A	Comments
12.	Verify that the accuracy of prepared standards is periodically checked by comparison with a standard from an independent source. Additionally, verify that a second source standard (initial calibration verification or (IVC) after the initial calibration and the responses of the second source calibration and the standards are compared against one another.	Section .7.3		Un-Sat		
13.	Verify that pH meters, balances and turbidity meters are calibrated daily with NIST traceable reference material. In addition ensure the following calibration frequencies are maintained: • Analytical Balances – every 12 months entire range) • Electrometer/pH – prior to use and once every four hours of use (calibrated with three buffer solutions)	Section .7.3	Sat			
14.	Verify that Gas Chromatography user range calibrations are initiated by obtaining a three or five point calibration curve, consisting of all compounds of interest plus a calibration blank.	Section .7.6.1	Sat			
15.	Verify that the laboratory participates in the EPA-LV/EMSL Interlaboratory Comparison Program.	Section 9.2.2,	Sat			
16.	Verify that when Gas Chromatography and Mass Spectrometry is performed the following operational parameters are adhered to satisfy analytical requirements associated with the determination of organic compounds in water and soil sediment: • Documentation of GC/MS mass calibration • Documentation of GC/MS response factor stability • Internal standard response and retention time	Section 7.6.2		Un-Sat		
17.	Verify that water utilized to prepare most LCSs analysis is analyzed for conductivity and water dispensing stations are tested on a weekly basis and results are recorded on the Water Conductance Log sheets	Section 9.2.2,	Sat			

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:		Location:				Evaluation Date(s)
Item	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
18.	Verify that the laboratory possesses a valid radioactive materials license.	Section 9.2.2,	Sat			
19.	Are efficiency control charts plotted on a daily basis, reviewed by the QA/QC department once tri-monthly, when either graph value to be reported falls on or above the +2 sigma or on or below the -2 sigma is the QA department notified?	Section 9.4.2	Sat			
20.	Review and verify that for Method 8000B per section 8.7.5 control limits are update semi-annually. Additionally, review and verify the frequency in which laboratory control charts are updated.	Section 9.4.1		Un-Sat		
21.	During Matrix Spike Sample Analysis, at what concentration percentage is each analyte in order to be within the linear range of the spiked sample solution. In addition is the acceptability of the control limit for a spike between 75-125% recovery.	Section 9.2.2	Sat			
22.	Verify that analytical spike sample analysis is being added after samples are prepared and prior to analysis and are run at a frequency of 5%.	Section 9.2.2	Sat			
23.	Verify that Laboratory Control Samples are ran independently with every batch of analysis and utilized for the verification of the internal standard from which the calculations are made.	Section 9.2.2	Sat			
24.	Verify that two (2) standard deviations are used for 95% confidence intervals during the calculation of control charts for the ICAP, and for each batch of samples analyzed the following QC checks are initiated: • At least one blank analyzed • At least one LCS (spiked with all reported analytes • MS/MSD pair analyzed • One sample duplicate analyzed • One sample dilution (dilution factor =5) • Initial multi-point calibration (3 to 6 standards plus a calibration blank) • One-point calibration verification standard compared against the initial calibration curve • Second source calibration verification standard. • A interference check standard at the beginning and end of the run • Drift check standard analyzed between every 10 field samples and at end of analysis run	Section 500	Sat			

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
25.	Verify that tracking of standards, chemicals, and reagents used in inorganic chemistry are logged in a bound logbook and the following information is maintained within: a. Date chemical/regent is opened b. Standard number c. consecutive numbered tape d. Identification e. Manufacturer, lot number etc. d. Mixing information e. noted mixing instructions f. Expiration date g. shelf life instructions f. Numbering system	Section 10.3	Sat			
26.	Ensure that Level 2 reviews of data packages include the following: • Group leader independent review • Calibration data are scientifically sound, appropriate to the method and completely documented. • QC Samples are within established guidelines • Quantitative identification of sample components is correct • Quantitative results are correct • Documentation is complete • Data package is complete.	Section 10.3	Sat			
27.	Review and verify that data reduction, validation and reporting are entered into the LIMS.		Sat			
28	Review and verify Paragon laboratory safety protocols. Are safety showers, fire extinguishers, etc., inspected? Additionally, verify the following: • Hazard Communication Program including MSDS use. • Use disposal of chemical reagents, chemical standards, and analysis samples • Medical surveillance program including physical examinations of employees			Un-Sat		
29	Is a record of Preventative Maintenance kept in the instrument log book for each piece of analytical equipment and is the tasked performed, date, and the person(s) performing the PM task logged into the log book		Sat			

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
30.	Verify that Level 2 reviews are structured to include 10 percent checks of calibration data and QC sample results and the results are against bench sheets. Additionally, when discrepancies Level 2 data packages are found, verify that an additional 10 percent of the samples are checked against bench sheets.	Section 10.4,	Sat			
31.	Verify that the following internal audits are performed to assess and document performance of the laboratory staff in the following frequencies: a. Monthly Systems Audits	Section 11.1,		Un-Sat		
32.	Review and verify that performance audits are documented and include the following: • Documentation of refrigerator blanks • Inspection/surveillance of temperature logbooks for refrigerators and ovens • Calibrations of mechanical pipettes	Section 11.1		Un-Sat		
33.	Are audit results and subsequent corrective actions (e.g., follow-up) verified within two weeks of report issuance?	Section 11.1		Un-Sat		
34.	Review and verify the latest external systems audit of the following agencies: • State of Colorado Department of Health • State of Utah Department of Health • State of California Department of Health Services • State of Arizona Department of Health Services • US Army Corps of Engineers •	Section 11.1 Section 11.2.1	Sat			

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
35.	Verify the following licenses, accreditation and certifications are held and maintained as applicable to Washington Group's subcontract: • State of Colorado Department of Health • State of Utah Department of Health • State of California Department of Health Services • State of Arizona Department of Health Services	Section 11.3		Un-Sat		
36.	Review and verify nonconformance reports. Are NCR's sequentially numbered and tracked on a tracking log?	Section 13.1		Un-Sat		
37.	Verify that NCR's are reviewed and approved by the analysis group supervision and Quality Assurance.	Section 13.1	Sat			
38.	Verify that out-of-control events are monitored against laboratory and project specific QA/QC requirements. Additionally when an event is determined to be out of control, verify that that laboratory initiates the appropriate level of corrective action top preclude future recurrence.	Section 13.2		Un-Sat		
39.	Are laboratory personnel trained commensurate with their duties, position, and responsibilities?		Sat			
40.	Review and verify that Paragon participates in inter-laboratory evaluation programs as sponsored by the following agencies: • US EPA Water Pollution and Water Supply Study Audit Program • State of California Department of Health Services Hazardous Waste PE Program • Department of Energy (DOE), Office of Environmental Management (OEM) Quality Assessment Program • EPA National Exposure Research Laboratory Characterization Research Division • Environmental Resource Associates Proficiency Testing Program (quarterly)		Sat			

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
41.	Review and verify that training records for all analytical staff members are being documented and maintained. Ensure that training records include the following as a minimum: • Records of academic training pertinent to the employees work assignment • Summaries of training seminars attended while employed at Paragon • Results of comprehensive testing or training • Results of Health and Safety instruction received at Paragon • Results of proficiency demonstrations as specified in Section 14.2.2 of the LQAP • Current resume if available			Un-Sat		
42.	Review and verify that the laboratory waste disposal program. Verify the classification of waste generated by Paragon Laboratory e.g., Small Quantity Waste Generator (SQWG) or large quantity waste generator.	Section 16.1		Un-Sat		
43.	Verify that Chain-of Custody/sample security requirements include: • Sample receipt requirements • Sample verification • Sample log-in requirements	Section 5.2	Sat			
44.	Review and verify that the laboratory waste disposal program. Verify the classification of waste generated by Paragon Laboratory e.g., Small Quantity Waste Generator (SQWG) or large quantity waste generator.			Un-Sat		
45.	Visually inspect the waste storage area. Ensure the following: • Waste is labeled hazardous or non-hazardous • Containers labeled type, start time, waste stream • Satellite accumulation area is emptied frequently • Containers have secondary containment		Sat			

Washington

AUDIT CHECKLIST

QUALITY ASSURANCE

Organization:	Location:	Evaluation Date(s)

	Attributes	References Paragon LQAP	Sat	Un-sat	N/A	Comments
46.	Review and verify that training records for all analytical staff members are being documented and maintained. Ensure that training records include the following as a minimum: • Records of academic training pertinent to the employees work assignment • Summaries of training seminars attended while employed at Paragon • Results of comprehensive testing or training • Results of Health and Safety instruction received at Paragon • Results of proficiency demonstrations as specified in Section 14.2.2 of the LQAP • Current resume if available	Section 14.3		Un-Sat		
47.	Review and verify that Paragon participates in inter-laboratory evaluation programs as sponsored by the following agencies: • US EPA Water Pollution and Water Supply Study Audit Program • State of California Department of Health Services Hazardous Waste PE Program • Department of Energy (DOE), Office of Environmental Management (OEM) Quality Assessment Program • EPA National Exposure Research Laboratory Characterization Research Division • Environmental Resource Associates Proficiency Testing Program (quarterly)		Sat			

Paul Bell

From: Paul Bell [paul.bell@wgint.com]
Sent: Thursday, July 12, 2001 1:08 PM
To: Debra Henderer [henderer@paragonlabs.com]
Cc: Marta Green; April Sacha
Subject: Overdue Audit Response

Dear Ms Henderer,

Currently Paragon Analytics response to Washington Group International, Inc. Quality Assurance Audit Report No. RAC-V-01-01 is overdue. It is urgent that your response is submitted to us on time. Our client the US EPA Region 8 Quality Assurance Manager has inquired regarding your response. The deficiencies noted during the audit and the formal corrective actions being formulated by your company are important to us and our client. Since we have not received your response or a request for an extension, our client the US EPA has voiced some concerns regarding the status, disposition, and formal corrective actions regarding this audit. As you are aware it is important to maintain good working relationships with our clients, therefore please provide Washington Group International the status of your response, and the date in which your response will be submitted.

Sincerely,

Paul Bell

Washington Group International, Inc.
Regional Quality Assurance Manager

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 02 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 14.3 *Training Records states, "Training records for all staff members will be* maintained by the Paragon Quality Assurance Department. Training files may contain (but are not limited to) the following information:

1. Records of academic training pertinent to the employee's work assignment
2. Summaries of any training seminars attended while employed at Paragon
3. Any test results for examinations taken at Paragon
4. Records of Health &Safety instruction received while at Paragon
5. If available, a current resume of the employee.

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: James M. Burr DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE		VERIFICATION OF IMPLEMENTATION	
Accept [ ]		Accept [ ]	
Reject [ ]		Reject [ ]	
		Not Required [ ]	
SIGNATURE/TITLE	DATE	SIGNATURE/TITLE	DATE

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 02 Page 2 of 2

FINDING: Contrary to the above requirements, it was determined that:

There is no objective evidence that Paragon Laboratory personnel have received laboratory department specific training or checklist thereof. Additionally, credentials attesting to the education, qualifications, and resumes of various staff personnel were either missing or incomplete. Further review of training records indicated that laboratory analysts/ technicians do not have documentation on file indicating that they have completed LQAP training, RCRA Waste training, etc. U.S Environmental Protection Agency Method SW-846 8000B mandates that the results of an analysts initial proficiency demonstration be posted to the individual training file or included in training records.

RECOMMENDED CORRECTIVE ACTION:

Washington Group International, Inc Response Action Contract in support of the U.S. EPA mandates strict compliance to EPA Methods and laboratory protocols. Training records should be updated to document training proficiencies, and the results of training proficiencies included in each analyst file. In general, training records provide the necessary assurance that laboratory personnel are trained, qualified and that they are proficient at their assigned task. Paragon Laboratory QA Manager should assess all training records and update all personnel training files as specified in LQAP Section 14.2.2.2 and SW-846 8000B.

Washington

June 08, 2001

Debra Henderer
Quality Assurance Manager
Paragon Analytics, Inc.
225 Commerce Drive
Fort Collins, CO. 80525

SUBJECT: **Washington Group International, Inc. Quality Assurance Audit Report No. RAC-V-01-01 of Paragon Analytics, Inc.**

Dear Ms. Henderer:

Enclosed for your review and subsequent response is the Washington Group International Inc. Quality Assurance Audit Report No. RAC-V-01-01 of activities at Paragon Analytics, Inc. located in Fort Collins, Colorado. The audit was conducted on May 08, 2001, to verify, by examination and evaluation of objective evidence, the ability of your Laboratory to provide Chemical Analytical Analysis. In addition, the scope of this audit was inclusive of verifying Paragon Analytics', Inc. capability to perform work as stipulated in the October 18, 1999 Subcontract 1D9-4994-SC01.

Based on the overall results of the audit, and in the opinion of the audit team, it appears that Paragon Analytics, Inc. has some minor programmatic problems as identified in the attached report that will require immediate corrective action.

This audit investigation covered (2) separate scopes of work. Since each of the respective work scopes were uniquely interrelated, the audit report is therefore subdivided into subsections which are inclusive of the following:

1. Compliance to current Chemical QA Program and applicable EPA requirements

2. Compliance to existing Subcontract 1D9-4994-SC02 Items

The audit resulted in seven (7) Quality Findings and two (2) Observations, which are documented in the attached report. Upon completion of corrective action implementation of each itemized post-award survey item, those items shall be forwarded with objective evidence with the completed audit responses. It should be emphasized that the following items must be addressed in a concise manner for each of the Quality Findings and Observation:

a. The steps, which have or will be taken to correct the condition reported;
b. The root cause that led to the condition reported;
c. The steps taken to prevent recurrence;
d. Lessons learned (if applicable);
e. The dates when indicated action was or will be completed.

Washington

Corrective Actions to all items requiring response shall be both concise and to the point.

The "original" audit report is attached for distribution to the appropriate personnel for inclusion of the required responses. Please submit your responses in the spaces provided on the attached "original" form. The original form should then be transmitted back to the Regional Quality Assurance Office for evaluation.

Should you have any questions regarding our approved vendor program, please contact me at (303) 843-2022.

Sincerely,

Washington Group International

David C. Lambert Laurem. Bem for David C. LAMBERT

DCL

Washington

WASHINGTON GROUP INTERNATIONAL, INC. QUALITY ASSURANCE AUDIT REPORT NO. RAC-V-01-01

Date 05/08/01

TO: Ms. Debra Henderer

FROM: David C. Lambert

LEAD AUDITOR:
(Signature) Paul M. Bell for David C. Lambert

AUDIT DATES: May 08, 2001

RESPONSE DUE DATE: July 8, 2001

ORGANIZATION Washington Group International, Inc. (Denver Regional Office)

ACTIVITY AUDITED: Paragon Analytics, Inc. Laboratory Quality Assurance Activities

PURPOSE/SCOPE: The scope of this audit was to evaluate Paragon Analytics Inc. implementation of laboratory quality program for activities and environmental testing protocols being performed at their facility in Fort Collins, CO. This audit was performed in support of the U.S. EPA Response Action Contract (RAC). These projects are inclusive of the Vasquez Boulevard/Interstate-70 (VB/I-70) site in Colorado, the Intermountain Waste Oil Refinery (IWOR) and the Eureka Mills site in Utah. The audit was initiated to verify compliance with Quality Assurance guidelines specified in both the VB/I-70 Phase IIIB QAPP and the IWOR Phase I QAPP.

AUDIT TEAM:
- Team Leader – D. C. Lambert
- Auditor - P. M. Bell
- Subject Matter Expert – A. Sacha

PERSONNEL CONTACTED DURING AUDIT:

Name	Title
See Attachments A and B	

SUMMARY:

The purpose and scope of the audit was presented at a pre-audit conference held on May 08, 2001, at Paragon Analytics facility located in Fort Collins, CO. The audit was performed in accordance with a written checklist of applicable laboratory QA program requirements. The audit results were derived based on interviews of personnel, review of records and logbooks, inspection of instruments, and the evaluation of QA Program procedure implementation. Audit results were presented to the appropriate Paragon Analytics, Inc personnel at the post-audit conference held on May 08, 2001.

The audit resulted in seven (7) minor Findings and two (2) Observations which are included in the attached report. With the exception of the noted Findings and Observations, the audited Laboratory

QA Program elements and criteria were determined to be in compliance with the QA program requirements and effectively implemented.

The audit team would like to thank all Paragon personnel contacted during the course of this audit.

The following good laboratory practices or noteworthy items were observed during the audit investigation and all responsible personnel should be commended for their professionalism.

- All employees are provided with dosimeter badges to be worn while in radiation areas.
- General laboratory housekeeping was good throughout the laboratory.
- Current staffing levels and evening/weekend coverage are excellent in regards to urgent turn-around times.
- Internal Chain-of Custody forms used for sample receipt to analysis to archival to disposal are organized and fully implemented.
- Good chemical hygiene was observed by the use of MSDS sheets, clear labeling of chemicals, solvents and standards. Containers in use were noted to retain the appropriate custody log-out documentation inclusive of the analyst initials and opened date on the container.
- The waste generation and disposal program currently in place is outstanding.
- All customer service provided to date by the Project Manager has been excellent.

In conclusion, the Paragon Analytic's Laboratory sample analysis and data validation is within acceptable limits to meet Washington Group International Inc. needs, provided the deficient items addressed throughout this audit report are satisfactorily corrected and verified through follow-up.

1. ORGANIZATION AND RESPONSIBILITIES

The organizational structure is adequately described in the Paragon Analytics LQAP, Section 2, and further illustrated in Appendix A of the LQAP. Activities and responsibilities are further defined and delineated in the LQAP.

Satisfactory compliance.

2. LABORATORY QUALITY ASSURANCE PROGRAM

The Paragon Analytics' Laboratory Quality Assurance Plan (LQAP Revision 4, dated 02/99) was reviewed. The frequency of internal reviews and revisions to the LQAP as stated are not being performed within the established frequency of once every two years. Review of Paragon Analytics LQAP indicated that many stated procedural requirements are not currently being practiced in the laboratory. A review of LQAP Section 16.2 revealed that Paragon was previously classified as a small quantity waste generator whereas now, Paragon is classified as a large quantity waste generator. Further review of Paragon LQAP, Section 15.1, stated that all laboratory employees who engage in laboratory activities are required to submit to annual physical examinations in accordance with the Laboratory's Medical Surveillance Program.

Nine (9) Laboratory Standard Operating Procedures (SOPs) were reviewed. SOP 409, Revision 0, (PCB Analysis), and SOP 525, Revision 4, (GC/MS VOA Analysis) were not up-dated bi-annually as specified in Paragon LQAP Section 1.5.2.

Additionally laboratory control limits and the associated control charts were reviewed. However, laboratory control limits and the control limit update frequency were not being re-calculated annually or semi-annually as required by US EPA Method SW-846-8000B, Section 8.7.5. During this audit, there were no records or personnel files to substantiate whether these programmatic elements are currently being implemented.

Reference Audit Finding Report (AFR) No. 01

3. QUALITY ASSURANCE OBJECTIVES

The objectives specified and defined within the Paragon Analytic's Laboratory Quality Assurance Program, Standard Operating Procedures and Program Specifications were reviewed during this audit. Review of various quality-affecting documents indicated that laboratory quality assurance objectives are being met through controlled distribution, preparation, and completion of laboratory protocols, with the exception of items identified throughout this report.
The majority of the laboratory activities were in compliance with laboratory procedures, with the exception of documents such as; (LQAP annual review, control limit calculations, and training records) which do not currently meet the objectives outline in Revision 4 of the LQAP.

Reference Audit Finding Report (AFR) No. No. 02

4. SAMPLE PRESERVATION, HOLDING TIMES AND HANDLING PROCEDURES

Sample preservation, holding times and handling procedures were reviewed. The laboratory sampling, preservation and handling protocols were assessed to ensure that scientific data is legally defensible and are in accordance with the protocols specified by USEPA Contract Laboratory Program.

Satisfactory compliance.

5. SAMPLE CUSTODY

Sample Internal Chain-of-Custody compliance was verified by visual inspection of the Sample Custody receipt and storage area. All sample custody activities inclusive of chain-of-custody, data validity, checkout and storage were verified as meeting the appropriate U.S. EPA requirements.

Satisfactory compliance.

6. ANALYTICAL PROCEDURES

Analytical Procedures were reviewed to verify compliance to the analytical protocols prescribed by various EPA Methods and compliance to the detailed requirements specified in each respective procedure. During the course of the audit, the audit team noted observations regarding analytical procedural protocols as follows:

- There is currently no solvent testing program in place (as specified by LQAP Section 17.2)
- Monthly supervisory reviews of laboratory logbooks are not being performed on a routine basis

Unsatisfactory Compliance

Reference Audit Observation Report (AOR) No.1

7. CALIBRATION PROCEDURES AND FREQUENCY

Calibration procedures and calibration frequencies were reviewed. The requirements for the calibration of laboratory scales/balances, and the calibration of instrumentation used throughout the laboratory was verified and validated against instrument calibration logs. Calibration frequencies are being maintained as well as, calibration stickers were verified as being affixed to instruments that required calibration.

Satisfactory Compliance

8. PREVENTIVE MAINTENANCE

The Paragon Preventative Maintenance Program was reviewed for adequacy and effectiveness. During the audit, a broken and/or not in use GC/MS pump and GC OI Purge and Trap was observed in an auspicious location. Further investigation indicated that the GC/MS pump and GC OI Purge and Trap were not labeled with the appropriate status indicator or tag-out tag as specified by SOP 319.

Unsatisfactory

Reference Audit Finding Report (AFR) No. 4

9. QUALITY CONTROL PROCEDURES

Internal Paragon Laboratory Quality Control Procedures were reviewed to determine the in-house systematic process controls implemented to measure and detect errors or out-of-control events. In-house quality controls are defined and implemented through various procedures. The criterion that is used to measure and analyze environmental data includes measurements of accuracy and precision. However, the control limit measurements that are required to reflect the degree to which the measured value approximates the actual or true value for a given

parameter and the control limits which influence bias in measurements are not being updated semi-annually or annually for some methods as required by EPA Method Protocols.

Unsatisfactory

Reference Audit Finding Report (AFR) No. 3

10. DATA REDUCTION, VALIDATION AND REPORTING

Data reduction, validation and reporting of information throughout the laboratory was reviewed and verified. Work Order No. 0103075 was reviewed. During the audit team's review the following observations were noted:

- Many organic laboratories were missing the annotation of the amounts of various standards added to samples during prep or analysis on the run log books
- Corrections to sample extraction and preparation laboratory worksheets for ignitability or GC pesticide data were not corrected with a single line through and initial and date.
- Manual integration was not being documented properly by analysts. A review of GC/MS SVOA and Pesticide data indicated that the "before and after" reason for integration and subsequent initial and date are missing.
- Case narratives are incomplete. A review of GC/MS SVOA narrative revealed that dilutions were initiated for WGI samples. However, the case narrative did not provide an explanation or reason as to why the dilutions were necessary, and an explanation ascertaining why undiluted samples did not have target compounds over the linear range.

UN-Satisfactory

Reference Audit Observation Report (AOR) No.1

11. PERFORMANCE AND SYSTEMS AUDITS

This verification included the review of performance and system audit schedules and completed audits.

The laboratory initiates two types of audits used to verify and assess laboratory compliance. A review of Paragon's audit program indicated that laboratory audits are being performed. However, internal performance and systems audits are not being performed at the frequency of once per month as specified in the LQAP.

Unsatisfactory compliance.

Reference Audit Finding Report (AFR) No.6

12. QUALITY ASSURANCE REPORTS TO MANAGEMENT

Reports to management were verified by review of nonconformance reports. The audit team reviewed various nonconformance reports and corresponding dispositions. Routine NCR dispositions such as; "use-as-is", "reject" and/or "repair" are not marked on the NCR form. Objective evidence of the disposition process indicated that in many cases the disposition was recorded as "Document in a Narrative". Further investigation indicated that in most cases, the narrative is undefined and is not attached or part of the disposition and closure of the NCR.

The NCR system does not provide adequate confidence that the nonconformance reporting and subsequent corrective actions are being dispositioned to preclude recurrence and are being tracked from initiation through closure.

Unsatisfactory

Reference Audit Finding Report (AFR) No.5

13. CORRECTIVE, ACTIONS

Laboratory Corrective Actions were reviewed. The corrective action program is in place. However, a review of audit results and subsequent corrective actions indicate that follow-up of corrective action implementation strategies are not being initiated within two weeks of report issuance as procedurally required. A review of the audit log indicated that a series of audits were performed in 1999 and 2000. The corrective actions to these audits were not noted as being either closed or that the corrective actions were completed.

UnSatisfactory

14. PERSONNEL TRAINING

Washington Group International was provided Paragon Training Documentation records for review. There was no objective evidence to substantiate department/laboratory specific training or subsequent checklists. Review of training records indicated that there was missing documentation attesting to the analytical staff's credentials (i.e., resumes, educational backgrounds, diploma's etc.) Additionally the following training records were noted as being incomplete: required Paragon LQAP training, Radiation Training RCRA Training etc. The training documentation that was reviewed did not summarize each analyst initial proficiency demonstrations (as specified in SW-846 and Paragon LQAP, Revision4 Section 14.2.2.2)

UnSatisfactory

Reference Audit Finding Report (AFR) No. 02

15. LABORATORY SAFETY

The Paragon Laboratory Safety protocols were reviewed by both visual inspection of laboratory areas and of in place programs. In general, the laboratory safety programs and personnel exhibit adequate knowledge to safely perform their assigned duties. Health and safety training was reviewed for various laboratory personnel. The Paragon medical surveillance program, which is inclusive of an annual physical examination for all employees, engaged in laboratory activities, is required by procedure. Training records indicate that no Paragon personnel have been given an annual physical as specified in the LQAP.

Unsatisfactory.

Reference Audit Finding Report (AFR) No. 02

16. LABORATORY WASTE DISPOSAL

The laboratory waste disposal was reviewed for various waste streams. The waste streams that are being generated are now of significant enough quantities to classify the laboratory as a large quantity waste generator. Currently the LQAP Section 16.2 classifies Paragon Laboratory as a small quantity waste generator, which does not coincide with the current waste generator classification.

Unsatisfactory

Reference Audit Finding Report (AFR) No. 01

17. PROCUREMENT CONTROL

Various procurement records were reviewed to assure legibility, traceability to associated items and, that they accurately reflect the work accomplished. Procurement records indicate that secondary source standards are being purchased from a different suppler than primary standards. Additionally, some procurement documents are not being reviewed or approved by cognizant supervision for quality affecting requirements such as, Certificates of Calibration, certificates of purity, NIST traceability etc.

Unsatisfactory Compliance.

Reference Audit Observation Report (AOR) No. 01

222

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 01 Page 1 of 2

ACTIVITY: Environmental Laboratory Audit

CLIENT: U.S EPA Response Action Contract (RAC)

ORGANIZATION: Paragon Analytics Incorporated

REPLY DUE DATE: 7/8/01

STATEMENT OF REQUIREMENTS: Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, Section 1.5.1 states, "The LQAP is main guidance document for laboratory operations when there exists no other project or program-specific requirements to which the laboratory must conform. This document will be reviewed and updated at a minimum frequency of once every two years or more frequently if there are significant changes in procedures or capabilities in the laboratory."

FINDING: Contrary to the above requirements: See Attached Page 2

Finding Classification: [ ] Major [X] Minor PAAA Reportable Yes [ ] No [X]

RECOMMENDED CORRECTIVE ACTION: See attached page 2.

You are requested to further investigate the finding(s) to identify the cause and effect of the condition(s) in order to determine the extent of corrective action required. The results of the investigation are to be considered in your reply.

AUDITOR: Laura M. Barr DATE: 06/08/01

CORRECTIVE ACTION RESPONSE:
(Attach additional sheets as necessary)

A. Action taken/proposed to correct findings:

B. Cause of Condition and Corrective Action to prevent recurrence:
Cause:

Corrective Action:

C. Completion Dates: (A:_____) (B:_____)

SIGNATURE_____ TITLE_____ DATE_____

EVALUATION OF RESPONSE		VERIFICATION OF IMPLEMENTATION	
Accept [ ]		Accept [ ]	
Reject [ ]		Reject [ ]	
		Not Required [ ]	
SIGNATURE/TITLE	DATE	SIGNATURE/TITLE	DATE

222

Washington	WASHINGTON GROUP QUALITY ASSURANCE AUDIT FINDING REPORT	AUDIT NO.: RAC-V-01-01 AFR No.: 01 Page 2 of 2

FINDING: Contrary to the above requirements, it was determined that:

1. Paragon Analytics, Laboratory Quality Assurance Plan Revision 4, dated 02/99, has not been revised since February 1999. The Paragon Analytics, Laboratory Quality Assurance Plan has not been updated or revised since February 1999 which exceeds the minimum review and updated frequency as specified in the LQAP. During the course of the audit, Washington Group had noted many discrepancies between what was stated in the LQAP and what is currently being practiced in the laboratory.

2. The following discrepancies were noted:

   Paragon Analytics LQAP Revision 4 Section 16.2 – Laboratory Waste Disposal

   Waste Storage: "Paragon is classified as a small quantity generator, and generates between 100kg and 1000 kg of waste per month. Because of this rate of waste generation, waste materials created at the laboratory may accumulate on the site for a maximum of nine months, depending upon location of the Temporary Storage and Disposal Facility." Contrary to this requirement, Paragon's waste generator classification has changed from a small quantity generator to now a large quantity waste generator, which is not accurately reflected in Section 16.2 of the LQAP.

   Paragon Analytics LQAP Revision 4 Section 15.1 – Laboratory Safety

   Health and Safety Training – "The goal of Health and Safety (H&S) training is to ensure that the laboratory personnel have adequate knowledge to safely perform their assigned duties. This training is presented by laboratory's H&S Officer Health and Safety training is provided to each employee as soon as possible after beginning work. The components of this course include, but are not limited to the following:

   - An explanation of the Medical Surveillance Program, which includes annual physical for all employees engaged in laboratory activities."

   Standard Operating Procedures LQAP Revision 4, Section 1.5.2

   "Standard Operating Procedures (SOPs) are documents that describe in detail how laboratory procedures will be performed by the staff. SOPs will be reviewed and updated at a minimum frequency of once every two years or more frequently if there are significant changes (e.g., SW-846 update)."

   Contrary to the above requirement, biannual updates or revisions to the following Standard Operating Procedures were not revised at the minimum biannual frequency as specified:

   SOP 409, Revision 0, dated 02/15/1999– Analysis of Polychlorinated Biphenyls (PCBs) By Gas Chromatography – Method 8082

   SOP 525, Revision 4, dated 02/12/1999 – Determination of Volatile Compounds By Gas Chromatography/Mass Spectrometry – Method 8260B and Method 624

RECOMMENDED CORRECTIVE ACTION:

Paragon Analytics Inc. should revise the LQAP to reflect the current manner in which business is being conducted in the laboratory. Standard Operating Procedures should also be revised in a timely manner. Since the LQAP is the basic document that represents an overview of laboratory functions, these procedural protocols should accurately reflect the methodologies used throughout the laboratory.

Washington
Government

5555 Greenwood Plaza Blvd., Suite 100
Englewood, Colorado USA 80111
Phone (303) 843-2000 • Fax (303) 843-3334

Transmittal Letter

Project Name:	Control No.:	W.O. No.:
RAC Contract No. 68-W7-0039	Date:	4994

To:	REFERENCES
Tony Medrano EPA Region VIII/8EPR-SR 999 18th Street, Suite 500 Denver, CO 80202-2466	Name: Equipment No.: Purchase Order No.: Vendor Order No.:

X TRANSMITTED HEREWITH	RETURNING FOR STATUS NOTED
___ Review and comment ___ Approval ___ Record ___ Information _X_ As requested ___ Other	___ Reviewed A ___ Review as noted B ___ Resubmit C ___ For information D ___ Other _____ E

ITEM	QUANTITY	TITLE/DESCRIPTION
1	1	DRAFT Audit Response from Paragon Analytics Inc.

DISTRIBUTION:	REMARKS/INSTRUCTIONS:
L. Lloyd – EPA	By: Paul M. Bell Name: Paul Bell Title: Regional Q/A Manager

PARAGON ANALYTICS, INC.
225 COMMERCE DRIVE
FORT COLLINS, COLORADO 80524
303 460 0201 PHONE
303 460 7538 FAX

FACSIMILE TRANSMITTAL SHEET

TO:	FROM:
Paul Bell	Debra Henderer henderer@paragonlabs.com
COMPANY:	DATE:
WGI	7/23/01, 1250 hr
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER:
303 843 2208	7

X URGENT --PLEASE DELIVER UPON RECEIPT X PLEASE REPLY

Paul—

Attached for your review please find a draft of the letter that you requested. Please let me know if you would like any changes made. You may reach me at 303 460 0201 on Monday (home office)

Thank you.

Debra Henderer

DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT

July 23, 2001

Mr. Paul Bell
Washington Group International
5555 Greenwood Plaza Blvd., Suite 100
Englewood, CO 80111

RE: On-Site Audit of Paragon Analytics, Inc. – May 08, 2001
Paragon's Corrective Action Plan For Quality Assurance Audit Report No. RAC-V-01-01

Dear Mr. Bell:

On June 12 Paragon received Washington Group International's audit report of June 08. We have reviewed the seven (7) minor Findings and two (2) Observations and I am writing to provide Paragon's proposed corrective action plan. Per our agreement of July 19, Paragon will submit a final corrective action report and supporting documentation to demonstrate closure of all Findings and Observations by September 30.

Following are Paragon's preliminary responses to the seven (7) minor Findings and two (2) Observations.

AFR No. 1

Root Cause of Finding: Paragon's Laboratory Quality Assurance Plan (LQAP), Revision 4, was published in February 1999. Paragon acknowledges that the LQAP should have been revised by February 2001, per our internal requirements. As Revision 5 has not yet been published, current

laboratory practices are not consistently reflected. In particular, Sections 16.2, 15.1, and 1.5.2 do not reflect current practices.

Paragon acknowledges that SOPs 409 and 525 should have been revised in February 2001, per our internal requirements. Paragon notes that current practices are compliant with the SW-846 methods referenced by these two (2) SOPs.

Proposed Corrective Action Plan: Paragon will review and revise all sections of the LQAP and SOPs 409 and 525 to reflect current practices. Paragon will provide documentation of the revised documents by September 30, 2001.

AFR No. 2

Root Cause of Finding: Paragon acknowledges that training files are not complete for all employees and that language in our LQAP (section 14) must be revised to reflect current organization of training records.

Proposed Corrective Action Plan: During the past 18 months, the QA Department has focused on reorganizing its system of filing and tracking training records. Training records are now organized into three (3) areas: quality assurance, health and safety, and departmental. Each employee has two (2) dedicated training files: quality assurance and health and safety. Paragon will continue to organize and document training records for each employee to ensure that each employee' individual file contains: academic qualifications; training seminars; test results; and a resume or qualifications form.

Training records are also organized according to topic (e.g., SOP review, LQAP review, IPR, departmental training) and these kinds of records are filed in separate binders, not in the employee's individual file. Paragon believes that some of the auditors comments recorded in this finding may be the result of a misunderstanding. The auditors were provided objective evidence of departmental training (e.g., IPRs, method training); however, these documents were organized according to method/topic and were not filed in each employee's file as expected. Paragon apologizes for the confused presentation.

In addition to the physical reorganization of training records, Paragon is developing a database interface that will supplement and/or replace the checklists, Word documents and spreadsheet system currently used to manage and track training requirements.

Paragon will review and revise the language in the LQAP, Section 14, to reflect current organization and tracking systems for training records. Paragon will provide documentation of the revised document by September 30, 2001.

AFR No. 3

Root Cause of Finding: Paragon's Laboratory Quality Assurance Plan (LQAP), Revision 4, was published in February 1999. As Revision 5 has not yet been published, current laboratory practices are not consistently reflected. As noted in this Finding, Section 9 of our LQAP does not reflect current practices for evaluating and updating control limits.

Proposed Corrective Action Plan: Paragon will review and revise the language in the LQAP, Section 9, to reflect current practices for evaluating and updating qc limits. Paragon's current practice is to evaluate control limits and warning limits for surrogates and spiking compounds every quarter. Intralaboratory historical control limits are updated as required (e.g., annually). Paragon notes that review and revision of intralaboratory historical may have no direct impact on our clients. As a federal programs laboratory we are most frequently required to evaluate data against predetermined qc limits, not intralaboratory historical limits. Paragon will provide documentation of the revised document by September 30, 2001.

AFR No. 4

Root Cause of Finding: The GC/MS pump and GC OI purge and trap apparatus were not properly tagged, per Paragon's SOP 319, to indicate that the items were out of service.

Proposed Corrective Action Plan: The QA Department placed out of service tags on these instruments on May 08, 2001 and verified that no other tags were required in the laboratory.

On June 12, The QA Department notified all Department Managers that their personnel must review SOP 319 and document review of this SOP.

Paragon will submit representative documentation of the SOP review by September 30, 2001.

AFR No. 5

Root Cause of Finding: Paragon believes that this Finding is the result of a misunderstanding and that the NCR process is effective as designed and implemented.

Proposed Corrective Action Plan: Following is Paragon's practice of initiating and completing NCR forms, which is compliant with our LQAP and SOP 928. The NCR Form is completed as follows:

1. The employee who discovers the discrepancy initiates the NCR Form and describes the cause of the discrepancy (Section I). The employee signs the NCR Form and forwards it to the Project Manager.
2. The Project Manager reviews the document to determine whether the client should be informed of the situation. The Project Manager and/or client determine the corrective action to be followed and records it on the form (Section II). The Project Manager signs the NCR Form and forwards it to the Quality Assurance Manager.
3. The Quality Assurance Manager reviews the document to determine whether the corrective action proposed and/or demonstrated is acceptable and adds additional comments, if necessary. The Quality Assurance Manager approves and signs the NCR Form.
4. The Quality Assurance Manager copies the completed NCR Form and distributes four (4) copies to the: department; Operations Manager; Project Manager; and Reporting Group, if applicable.
5. The case narrative has not been written at the time the NCR Form is initiated and completed. As designed, the NCR Form is written immediately and resolution is determined and demonstrated as soon as possible. The case narrative is written when the data and forms are compiled.
6. All work orders are reviewed by the department (two independent reviews); Reporting Group; and Project Manager. It is the responsibility of each of these groups to ensure that the disposition of the NCR Form is followed and documented in the case narrative and that the NCR Form is included with the work order.

Given these four (4) levels of review, Paragon is confident that the NCR process is effective. No corrective action is proposed for this Finding.

AFR No. 6

Root Cause of Finding: The schedule of internal audits presented was outdated and misleading. For example, the list of audits noted in the auditor's report included topics for internal audits that were not performed.

Paragon uses several kinds of documents as a script (or worksheet) for internal audits. These documents include SOPs, promulgated methods, forms, and/or formal checklists, as appropriate. Annotated copies of SOPs, promulgated methods, forms, and/or formal checklists are available in the Internal Audit Binder.

Proposed Corrective Action Plan: Paragon will revise the internal audit schedule to differentiate between internal audits that were actually performed and those proposed. In addition, Paragon will review SOP 937 to ensure that it describes current practices. Paragon will submit the revised schedule and SOP by September 30, 2001.

AFR No. 7

Please see Paragon's response to AFR No. 5.

AOR No. 1

Root Cause of Finding: Paragon's Laboratory Quality Assurance Plan (LQAP), Revision 4, has not been revised since February 1999. As Revision 5 has not yet been published, current laboratory practices are not consistently reflected. As noted in this Finding, Section 17 does not reflect current practices for receipt verification of standards, solvents and acids.

Proposed Corrective Action Plan: Purchase orders for routine items (such as standards, solvents, and acids) are not reviewed by the QA Department. The Department Manager is responsible for ensuring that the correct item has been ordered and received. As primary and secondary source standards are verified against each other upon receipt, a discrepancy by the vendor will be

detected and the standard returned immediately. Our experience demonstrates that the current system is effective and that review by the QA Department is unnecessary.

Paragon's practice for receipt verification does not involve concentrating solvents or acids to a reduced volume. Paragon only purchases solvents and acids of the highest quality (e.g., trace metals grade mineral acids, pesticide grade hexane, hplc grade water). Review of method blanks and TIC reports demonstrates no interferences/contaminants from solvents or acids. Therefore, Paragon eliminated the practice of analyzing reduced volumes of solvents.

Paragon's proposed corrective action plan is to update the LQAP to reflect current practices. Paragon will provide documentation of the revised document by September 30, 2001.

AOR No. 2

No response is required.

In closing, Paragon acknowledges that the minor Findings and Observations represent administrative issues that must be corrected. The items listed by the auditors do ***not*** affect Paragon's ability to produce compliant data. Paragon is committed to resolving the issues cited and will provide documentation of all corrective actions by September 30, 2001.

Paragon extends our thanks for your time and consideration of the proposed corrective actions. Please contact me at 970 490 1511 if you have any questions or need additional information.

Sincerely,

Debra Henderer
Quality Assurance Manager
Paragon Analytics, Inc.

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